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2012 / 15 15 AM 10: 39

August 14, 2012



Via Federal Express

United States Environmental Protection Agency - East

Attn: TSCA Section 8(e)

Room 6428

1201 Constitution Avenue, NW

Washington, DC 20004



Subject:

Notice in Accordance with TSCA Section 8(e): Results of a Combined Repeated Dose

Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar

Rats with 1-Vinylimidazol (CAS No. 1072-63-5)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats [Crl:WI(HAN) Charles River, Sulzfeld, Germany], administration via gavage, according to OECD Guideline 422, with 1-Vinylimidazol (CAS No. 1072-63-5), conducted by BASF SE, Ludwigshafen, Germany. The test substance is a monomer.

The test substance was administered to groups of 10 male and 10 female young Wistar rats (F0 parental generation) dissolved in drinking water, via daily gavage. The dose levels were 0, 5, 15 and 35 mg/kg body weight/day. About 2 weeks after the beginning of treatment, F0 animals were mated to produce a litter (F1). Mating pairs were from the same dose group. Pregnant females were allowed to give birth and the offspring was brought up until postnatal day (PND) 4. The study was terminated with the sacrifice of the F1 young adult animals on PND 4 and of lactating dams shortly thereafter.

The mid- and high-dose parental female animals (15 and 35 mg/kg bw/day) showed piloerection, semiclosed eyelids as well as reduced food consumption and body weight gain during the premating, gestation and lactation phases of the study.

Peri-postnatal survival of the mid- and high-dose offspring (15 and 35 mg/kg bw/day) was affected: the number of live-born pups and the live birth index was reduced (94 and 74%, respectively). Pups from these groups also had increased mortality rates as well as reduced body weights and body weight gains. In the high-dose group this included a complete loss of 2 litters. No test substance-related adverse reproductive/developmental findings were noted at 5 mg/kg.

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The Chemical Company

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The 94 offspring in the high-dose group (35 mg/kg bw/d) had an increased incidence of vascular defects including 10 cases of dilated aortic arch and aorta. Four cases of these changes were still noted at 15 mg/kg bw/day (in a total of 106 pups). At 5 mg/kg no such findings were observed.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra

Product Regulatory Center of Expertise, North America

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From: (973) 245-6693 Janet Cerra BASE 100 Park Avenue

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